

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
VICINAGE OF TRENTON

HANNAH LOVAGLIO, J.L. and B.L. , by next friend, Hannah Lovaglio,	:	
ERICA JEDYNAK, JEREMIAH JEDYNAK , and C.J. , by next friends, Erica and Jeremiah Jedynak,	:	
<i>Plaintiffs,</i>	:	Hon. Georgette Castner, U.S.D.J.
v.	:	Hon. Rukhsanah L. Singh, U.S.M.J.
KAITLAN BASTON , Commissioner of the New Jersey Department of Health, sued in her official capacity, and	:	Civil Action No. 3:23-cv-21803
NANCY SCOTTO-ROSATO , Assistant Commissioner for the Division of Family Health Services, sued in her official capacity,	:	
<i>Defendants.</i>	:	
	:	

**DEFENDANTS' REPLY BRIEF IN FURTHER SUPPORT OF THEIR
MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT**

MATTHEW J. PLATKIN
ATTORNEY GENERAL OF NEW JERSEY
Richard J. Hughes Justice Complex
25 Market Street, P.O. Box 093
Trenton, New Jersey 08625-0093
(609) 649-4574
jean.reilly@law.njoag.gov

Michael L. Zuckerman (N.J. No. 427282022)
Deputy Solicitor General

Jean P. Reilly (N.J. No. 021081997)
Assistant Attorney General

(counsel list continues on next page)

Amy Chung
Nathaniel I. Levy
Elizabeth M. Tingley
Deputy Attorneys General

Counsel for Defendants

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PRELIMINARY STATEMENT

Despite acknowledging that New Jersey’s newborn screening (NBS) program undoubtedly “saves children’s lives,” Opp. 2, Plaintiffs ask this Court to rule that all 50 States’ NBS programs have been violating the Constitution, to one extent or another, for decades. Yet they offer no persuasive account of how either their Fourth or their Fourteenth Amendment theories can state a valid claim, nor even how they can invoke this Court’s Article III jurisdiction despite seeking only prospective relief and having every opportunity to avoid the injury they allege.

Begin with Article III. Plaintiffs must show an injury-in-fact fairly traceable to Defendants (DOH). They cannot, because they can obtain destruction on demand—the same way someone cannot decline to join the “do not call” registry and then sue the telemarketer. That is consistent with settled precedent—and distinct from cases where a plaintiff is caught between two options that *both* cause injury.

Further, Plaintiffs cannot state a Fourth Amendment seizure claim because they lack a sufficient property interest in residual dried blood spots (rDBS). Indeed, Plaintiffs’ own initial demand that samples be destroyed in the absence of an affirmative retention request implicitly acknowledged that the type of ongoing possessory interest necessary to state a seizure claim against DOH is lacking here. While Plaintiffs now seem to suggest that *any* default rule is problematic, Opp. 30, that is untenable for a system that screens 100,000 babies each year.

Even assuming Plaintiffs have some residual possessory interest, DOH’s default rule—destruction at two years, absent an earlier request—is categorically reasonable under the special-needs exception, and no discovery or weighing of evidence is needed to find as much. Testing saves lives; false positives, false negatives, and late-onset manifestation are realities; quality control (QC), quality assurance (QA), and new-test development are salutary; retention is non-intrusive; and destruction of rDBS is irreversible, whereas retention is not. The compelling health needs the program serves far outweigh any burden on Plaintiffs’ interests.

The State respects that Plaintiffs have sincere moral and policy disagreements with the NBS program. But those disagreements do not suffice to invoke Article III, let alone state a valid constitutional claim. The FAC should be dismissed.

ADDITIONAL BACKGROUND

While Plaintiffs state that DOH’s new policy “can be reversed tomorrow,” Opp. 2, that is not quite right. On November 1, 2024, DOH began destroying all samples (except for de-identified positive samples) older than two years in the absence of an affirmative retention request. *See* FAC ¶¶ 87-92, 100-02; MTD 10 n.10. DOH expects that process to be completed next month. That is irreversible.¹

¹ The State contacted Plaintiffs’ counsel to seek clarification about whether to destroy or continue to retain the samples associated with their children, but counsel has not responded—underscoring that some default rule is always going to be necessary. *See infra* at 12. Erring on the side of caution, DOH continues to retain these samples, despite the fact they are now more than two years old, *see* FAC ¶ 12.

In addition, all NBS programs appear to retain rDBS beyond initial testing. Plaintiffs assert that “[s]ome states automatically destroy the blood after testing is complete,” but cite South Dakota as the lone example. Opp. 3 n.2. Yet according to South Dakota’s Department of Health, “leftover blood spots are destroyed within 60 days”²—roughly 45 days later than the deadline Plaintiffs demand here. In other words, no State does what Plaintiffs claim is constitutionally compelled—automatically destroying the sample when a baby is two weeks old, in the absence of an affirmative retention request. *See* MTD 5-6 & n.2 (many States retain samples for longer than two years, and not all States allow destruction on demand). And while a few courts have begun to weigh in, Plaintiffs’ theory that all 50 States’ NBS programs have been violating the Constitution (to one degree or another) for decades is still a new frontier of litigation. *See* MTD 6 n.5; Opp. 13.

ARGUMENT

I. The Voluntary Cessation Doctrine Does Not Apply Here.

Plaintiffs’ invocation of voluntary cessation principles (Opp. 9-12) is mismatched with this case. Voluntary cessation is an exception to mootness; it describes a “scenario” in which courts “are reluctant to declare a case moot” on the basis of actions defendant took “unilaterally after the litigation began.” *Hartnett v.*

² *See* South Dakota Department of Health, *Newborn Screening: Saving Babies’ Lives*, https://doh.sd.gov/media/k5ihbhwo/nbs_pamphlet.pdf (linked to from <https://doh.sd.gov/programs/newborn-screening/>).

Penn. State Educ. Ass'n, 963 F.3d 301, 306 (3d Cir. 2020). But DOH has never claimed that this case is moot. And while the State does contend that Plaintiffs lack *standing*, *see infra* at 5-8; MTD 14-19, standing and mootness are “two distinct justiciability doctrines,” *Hartnett*, 963 F.3d at 306, and voluntary cessation has no bearing on the former, *cf. Lutter v. JNESO*, 86 F.4th 111, 126 (3d Cir. 2023) (when a second complaint “add[s] factual allegations that arose after the original complaint,” Article III standing is “evaluated as of … the date [plaintiff] filed the second complaint”). So voluntary cessation has no role to play in this case.

Further, DOH’s changes are far from irrelevant to this litigation. *Contra Opp.* 2. As an initial matter, the FAC addresses those policy changes, acknowledging their relevance. *See, e.g.*, FAC ¶¶ 6-7, 77-125. Those changes themselves, moreover, bear on any analysis of both standing and the merits. It is hard to see, for instance, how this Court could engage in the category-level balancing required by the Fourth Amendment’s special-needs doctrine, *e.g.*, *infra* at 12-13, without assessing the DOH policy that is actually in place. Indeed, it is unclear how such an opinion could avoid being essentially advisory if it focused solely on a superseded policy.

In any event, while DOH has never claimed that its new policy is formally unalterable, there is no reasonable likelihood of reversion. *See, e.g.*, *Sutton v. Rasheed*, 323 F.3d 236, 248-49 (3d Cir. 2003); *Am. Freedom Def. Initiative v. Metro. Transp. Auth.*, 815 F.3d 105, 110 (2d Cir. 2016). Even apart from the State’s own

representations, the strongest indicator is that DOH is now voluntarily (and irreversibly) destroying two decades of samples, despite knowing Plaintiffs will continue to press their claims. That is hardly the kind of action consistent with an entity that hopes to possess or recreate a 23-year “stockpil[e],” Opp. 1.

II. Plaintiffs Lack Standing.

Plaintiffs do not dispute that they could obtain destruction of the relevant samples by sending a single email and thus fail to show standing. Where “a plaintiff seeks *prospective* (forward-looking) relief in the form of an injunction or a declaratory judgment, they must show that they are likely to suffer future injury” traceable to defendants. *Yaw v. Del. River Basin Comm’n*, 49 F.4th 302, 318 (3d Cir. 2022). And under settled precedent, a party cannot do so where they knowingly avoid an easy means of obtaining the relief they supposedly seek—as when one could easily opt-out of telemarketing calls but chooses not to. MTD 15-17 (collecting cases); *see also, e.g., Animal Legal Def. Fund, Inc. v. Vilsack*, 111 F.4th 1219, 1228 (D.C. Cir. 2024) (consumer who “reli[es] on labels” she knows to be “misleading,” rather than simply desisting from purchasing, suffers “self-inflicted injury” and lacks standing); *St. Louis Heart Ctr., Inc. v. Nomax, Inc.*, 899 F.3d 500, 504 (8th Cir. 2018) (recipient with “means and opportunity to opt out from receiving future facsimiles, but [who] simply declined to do so,” lacked standing). Here, Plaintiffs seek only prospective relief, FAC at 51-52, and they do not dispute that

DOH is already destroying samples older than two years; would have already destroyed the samples associated with the Child-Plaintiffs were their own preferences not unclear amid this litigation, *supra* at 2 n.1; FAC ¶¶ 12-13; and will destroy any samples on demand at any time after initial testing, *id.* ¶¶ 90-92. Because Plaintiffs can easily end the retention they challenge just by asking—yet choose not to—any injury from that retention is not fairly traceable to DOH. *See* MTD 14-17.³

Federal Election Commission v. Cruz, 596 U.S. 289 (2022), is not to the contrary. There, federal law restricted the use of post-election campaign funds to repay a candidate’s personal loan to his campaign. *Id.* at 293. That put a candidate on the horns of a dilemma: he would have to either suffer a monetary injury by not having his loan repaid, or suffer an alleged First Amendment injury by limiting the amount of his loan to fit the restriction. *Id.* at 293-98. Caught between that Scylla and Charybdis, opting for one instead of the other did not render the injury self-inflicted. *Id.* at 297-98. Here, by contrast, there is no false choice: Plaintiffs do not argue (nor could they) that both alternatives cause harm; they accept that they could obtain destruction effectively with the click of a button. While they may wish for a ruling with which they agree, such a ruling would not grant them anything they could

³ Some courts do not regard self-inflicted injury as injury-in-fact at all; others see it as a traceability problem. *See Buchholz v. Meyer Njus Tanick, PA*, 946 F.3d 855, 867 (6th Cir. 2020) (collecting cases). Whatever the label, standing is lacking.

not already obtain today—and “hope for nothing more than an opinion … cannot satisfy Article III.” *Haaland v. Brackeen*, 599 U.S. 255, 294 (2023).

Consistent with these cases, courts confronting challenges to the retention of rDBS have rejected such challenges for lack of standing where plaintiffs could obtain destruction on demand but declined to do so. *See Doe v. Adams*, 53 N.E.3d 483, 491, 498 (Ind. Ct. App. 2016); *Higgins v. Texas Dep’t of Health Servs.*, 801 F. Supp. 2d 541, 553 (W.D. Tex. 2011); MTD 15-16. Plaintiffs’ attempt to distinguish these cases is unpersuasive. Opp. 18 n.6. While the challengers in these cases were “worried about how … [retained] blood spot[s] could be used,” *id.*, they nonetheless lacked standing to bring their claims, at least in part, because they failed to “at any time request” destruction, which would obviate any concerns about potential uses, *Doe*, 53 N.E.3d at 498; *see Higgins*, 801 F. Supp. 2d at 553 (concluding plaintiffs lacked standing because they neither sought nor were “deni[ed] … information” about the use of stored samples, and neither sought nor were “deni[ed] … destruction”). Indeed, both cases dealt with claims for prospective relief; both found that challengers failed to obtain easily available destruction; and both determined that failure contributed to a lack of standing. Plaintiffs are thus incorrect in arguing that “every federal court” in related cases has found standing. Opp. 13.

Some final points bear noting. First, Plaintiffs largely disclaim a (speculative) challenge based on “what New Jersey may or may not do with the blood spots,”

clarifying that their asserted injury is only retention “without … informed consent.” Opp. 21; *cf.* MTD 17-19. But an end to retention is already what Plaintiffs (and any other parent) can obtain on request. Second, Plaintiffs’ reliance on the meaning of consent in motion-to-suppress litigation, Opp. 19, is a merits argument that sheds no light on standing. No one here claims that a criminal defendant lacks standing to challenge the introduction of evidence against him—whereas here, Plaintiffs invoke Article III jurisdiction to obtain destruction of samples that DOH already stands ready to destroy. *Cf.* FAC ¶¶ 90-92. Finally, Plaintiffs cannot satisfy Article III by hoping to represent proposed class members with positive samples, or any other party. *Compare* MTD 12 n.12, *with* Opp. 4 n.3. Parties associated with positive samples would have different interests (and different alleged burdens, because those samples are de-identified), and regardless, to represent a proposed class, Plaintiffs still must have standing themselves. *Frank v. Gaos*, 586 U.S. 485, 492 (2019).

III. Plaintiffs’ Fourth Amendment Claim Fails As A Matter Of Law.

Plaintiffs fail to state a Fourth Amendment seizure claim for two independent reasons. First, they cannot state such a claim at all, because they lack a sufficient possessory interest in rDBS. MTD 19-25. Second, no discovery is needed for this Court to conclude that New Jersey’s NBS program is categorically reasonable under the Fourth Amendment’s special-needs exception. *Id.* 25-37.

1. Plaintiffs err in claiming that they retain a sufficient perpetual possessory interest in rDBS, left over from an initial-testing process that they do not challenge, to exclude DOH from any temporary further retention. To start, their suggestion that New Jersey law designates rDBS as property is mistaken. *See* Opp. 23-24. Rather, while the Legislature considered doing so in the Genetic Privacy Act, it ultimately declined to. *See* MTD 21 n.15. Indeed, that Act expressly carves out rDBS, providing that its informed consent requirement “shall not apply to genetic information obtained … [p]ursuant to newborn screening requirements established by State or federal law.” N.J. Stat. Ann. § 10:5-45(a)(6).

Plaintiffs’ reliance on *Kanuszewski v. Michigan Department of Health & Human Services*, 927 F.3d 396 (6th Cir. 2019), and *Beleno v. Lakey*, 306 F. Supp. 3d 930 (W.D. Tex. 2009), is also misplaced. *See* Opp. 26. Neither decision addressed the question of a property interest under New Jersey law (naturally), nor did either discuss the special-needs exception. Both opinions, moreover, based their rulings on allegations of uses “unrelated to the purposes for which the blood was originally drawn,” *Beleno*, 306 F. Supp. 3d at 943; *see Kanuszewski*, 927 F.3d at 425 (“Plaintiffs allege that Defendants conduct research on children’s stored blood samples and seek to derive profit from the children’s samples … For this reason, Plaintiffs have plausibly stated a claim …”). But Plaintiffs here have disclaimed any such (speculative) allegation, *see* Opp. 21, and instead challenge DOH’s default rule,

which serves interests intrinsic to NBS and the specific child, *see* FAC ¶ 119 (only follow-up screening, QA/QC, and new test development). Accordingly, granting Defendants' motion here would not inherently conflict with either opinion.

Plaintiffs also err in relying on Fourth Amendment *search* cases. Opp. 24-25. Precedent makes clear that a privacy interest against unreasonable searches is "quite different" from a possessory interest that protects against unlawful seizures. *Arizona v. Hicks*, 480 U.S. 321, 328 (1987); *see* MTD 24. And any privacy interest at issue here is minimal, given not only that the Plaintiffs themselves do not challenge the initial blood draw, but also that residual spots are kept in a secure facility and used for only three purposes (follow-up screening, QA/QC, and new test development, with samples de-identified prior to the latter two uses in any event). Plaintiffs' references to DNA collection, Opp. 25-26, are particularly far afield and also inconsistent with their sensible concession that they are not bringing a wholly speculative challenge about "what New Jersey may or may not do with the blood spots," Opp. 21.

Plaintiffs' reliance upon *Skinner v. Railway Labor Executives' Association*, 489 U.S. 602 (1989), *see* Opp. 24, is also unavailing. There, the Supreme Court was referring to fluids in a person's body when it wrote that "[t]aking a blood or urine sample might also be characterized as a Fourth Amendment seizure, since it may be viewed as a meaningful interference with [a person's] possessory interest in his

bodily fluids.” *Id.* at 617 n.4. But DOH is not arguing that people lack a possessory interest in blood within their own bodies. Rather, the blood at issue here has already been taken out pursuant to a heel prick that Plaintiffs do not challenge, and the case is instead about whether DOH may retain that blood for two years in the absence of an express request to destroy it. *Skinner* offers no support for the theory that DOH’s default rule—destruction at two years rather than two weeks—is unconstitutional.

Nor do Plaintiffs effectively distinguish the excised-tissue cases, which further weaken their seizure claim. *See* MTD 22-23. The seminal case, *Moore v. Regents of the University of California*, 793 P.2d 479 (Cal. 1990), involved a conversion claim premised on the plaintiff’s asserted “possessory and ownership interest” in cells removed from his body during a splenectomy that he had authorized. *Id.* at 481, 487. California’s high court rejected this “novel” and “problematic” theory. *Id.* at 488-89. While *Moore* upheld an independent breach-of-fiduciary-duty claim against the doctor who removed the cells for failure to obtain informed consent, *id.* at 485-86; *see* Opp. 26-27, that does not support Plaintiffs’ Fourth Amendment seizure claim. *Moore* did not find (nor did it have to) that the challenger had a possessory interest in the removed cells; it simply determined that the plaintiff could sue his physician for breach of his “disclosure obligations” before obtaining consent to a medical procedure. 793 P.2d at 480. That does not bear on the question of whether Plaintiffs retain a possessory interest sufficient to raise a seizure

claim against DOH—and is otherwise inapplicable where, as here, DOH discloses the uses to which rDBS may be put anyway. FAC ¶ 89.

Finally, Plaintiffs’ arguments about the upshot of their initial destruction demands run into a logical inconsistency. While Plaintiffs initially demanded that DOH be ordered to destroy existing and future specimens absent an express request for retention, *see* FAC ¶¶ 147, 177, 179; *see also* Opp. 14-15 (stating “only an ‘opt-in’” system is “constitutionally sufficient”), they have since suggested that they “don’t want the default to be destruction,” *id.* 30. In other words, Plaintiffs originally (and correctly) acknowledged that there must be some default rule, and the parties simply disagreed about whether the Constitution mandates that default be destruction at two weeks rather than two years. But if Plaintiffs are now arguing that *no* default rule is necessary (or even permitted), that is plainly untenable: 100,000 babies are born in New Jersey each year, and there is no way for DOH to know what every family wants, least of all within two weeks, or going back over 23 years.⁴

2. Independently, though relatedly, the touchstone of the Fourth Amendment is “reasonableness,” *Brigham City v. Stuart*, 547 U.S. 398, 403 (2006), and DOH’s default rule of destruction at two years (absent an earlier request) for this public-

⁴ To be sure, DOH can invite each parent to share their preference, as it already does. *See* FAC ¶ 89. It cannot, however, force a parent to give an answer. *See supra* at 2 n.1. Nor can it ensure that every nurse, doctor, or staff member—almost none of whom work for the State—correctly obtains and transmits a parental preference for every birth. Some default rule is needed.

health program is categorically reasonable under the special-needs exception to the warrant requirement. Indeed, given the possibility of false negatives and late-onset conditions, *see* MTD 27-28 (*see also* Newborn Screening Alliance Br. 6-9 (ECF 44)); the fact that destruction is irreversible, MTD 32; and the other obligations competing for parents' time in the first two weeks of a child's life, *id.* at 33, that default rule is far more reasonable than Plaintiffs' destroy-at-two-weeks default.

Plaintiffs are incorrect that application of this exception "requires discovery." Opp. 31. Multiple courts, including this one, have dismissed Fourth Amendment claims under the special-needs exception without any discovery. *See, e.g., Cassidy v. Chertoff*, 471 F.3d 67, 87 (2d Cir. 2006); *Nicholas v. Goord*, 430 F.3d 652, 669, 672 (2d Cir. 2005); *Stehney v. Perry*, 907 F. Supp. 806, 823 (D.N.J. 1995). Consistent with that precedent, DOH is not asking this Court to weigh competing evidence, but simply to recognize that Plaintiffs cannot state a valid Fourth Amendment claim in light of the basic legal context, allegations in the FAC, and basic "legislative facts," MTD 4 n.1, *e.g.*:

- False positives and negatives are inevitable during any screening process, and disorders can manifest later in infancy or toddlerhood, MTD 5, 27;
- QA/QC, using de-identified rDBS, is legally required, MTD 30 & 34 n.20;
- New test development, using de-identified rDBS, is legally required, N.J. Stat. Ann. § 26:2-111; MTD 34 n.20;
- Destruction of rDBS is irreversible, MTD 32;
- Plaintiffs can avoid an alleged seizure by requesting that rDBS associated with them be destroyed, FAC ¶¶ 90-92; MTD 33; and,

- NBS is not a law enforcement program, and anyone who might be prosecuted on the basis of rDBS can move to suppress, raising an as-applied claim, *id.*

Those undisputed features alone establish that DOH’s policy serves legitimate public interests, unrelated to law enforcement, that far outweigh any intrusion on Plaintiffs’ interests. *See Neumeyer v. Beard*, 421 F.3d 210, 214 (3d Cir. 2005); MTD 26-37.

Plaintiffs’ arguments in favor of discovery fall short. *See* Opp. 34-37. Plaintiffs argue that discovery is needed to assess exactly how useful follow-up screening is, Opp. 34, but a court need not reduce that usefulness to decimal points to acknowledge that retention inherently enables follow-up screening, MTD 30-31, and that follow-up screening is a legitimate public interest unrelated to law enforcement, *see Neumeyer*, 421 F.3d at 214. Plaintiffs similarly argue that this Court should assess the exact number of rDBS necessary for QA/QC and new test development, Opp. 36, but they can hardly claim (and do not try to claim) that these are illegitimate interests, or that these interests could be effectively served by default destruction at two weeks. And Plaintiffs’ passing references to not knowing “what Defendants are actually doing with the retained blood spots,” Opp. 34; *see also* Opp. 36, are ancillary to what they have (properly) clarified as the non-speculative gravamen of their claim—not “what New Jersey may or may not do with the blood spots,” but what its default rule is, Opp. 21. While DOH would of course expect to prevail at summary judgment as well, Plaintiffs have not shown any basis for prolonging this dispute: just as their claims could be dismissed for lack of standing

and lack of cognizable possessory interest, DOH's two-year default policy also satisfies the Fourth Amendment's special-needs exception as a matter of law.

IV. Plaintiffs' Substantive Due Process Claim Fails Both On The Merits And For Lack Of Standing.

Plaintiffs offer little to support their substantive due process claim. Plaintiffs do not (and cannot) argue that DOH's retention policy implicates a parent's right to direct their child's upbringing. *See* Opp. 37-39; *cf. Troxel v. Granville*, 530 U.S. 57 (2000). Instead, they claim that retention infringes on a parent's right to direct their child's medical care, relying solely on one out-of-circuit decision. Opp. 38. But neither Plaintiffs nor *Kanuszewski* articulate *how* the retention of rDBS could be said to interfere with this general parental right.

As noted, retention serves limited but important public purposes: follow-up screening, routine lab QA/QC, and development of new tests. *Supra* 10; MTD 1; FAC ¶¶ 87-92, 104, 112. But none of these implicates medical care. The latter two—each of which uses de-identified samples—plainly do not. And while follow-up screening can provide diagnostic information that could *inform* care (*e.g.*, in the case of a late-onset disorder), retention that enables such screening is not the care itself. It remains the parents' prerogative—not DOH's—to choose to pursue such care or not. This claim fails as a matter of law and under Article III. *See* MTD 39-40.

CONCLUSION

This Court should dismiss the First Amended Complaint.

Respectfully submitted,

MATTHEW J. PLATKIN
ATTORNEY GENERAL OF NEW JERSEY

By: /s/ Jean P. Reilly
Jean P. Reilly (N.J. Bar. ID #021081997)
Assistant Attorney General

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